IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventors	**:**	**Patrick Rafter**
Application No.	**:**	**10/599,769 From PCT/IB05/51111**
Filed	**:**	**October 9, 2006**
For	**:**	**AUTOMATED MYOCARDIAL CONTRAST ECHOCARDIOGRAPHY**

APPEAL BRIEF

On Appeal from Group Art Unit 3768

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded October 9, 2006 at reel 018364, frame 0690.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-20 are pending in the application and stand finally rejected by the Office action mailed July 24, 2008. The claims being appealed are Claims 1-20.

IV. STATUS OF AMENDMENTS

A Preliminary Amendment was submitted with the entry of this application into the US national stage which amended Claims 1 and 5 of original Claims 1-20. Following a restriction requirement a first Office action was mailed on February 1, 2008 which rejected Claims 1-20. An Amendment was submitted in response on May 1, 2008 which amended Claims 1, 4, 15, 16, 18 and 19. Claims 1-20 are pending in the application and stand finally rejected by the Office action mailed July 24,

2008. A Notice of Appeal was filed on October 13, 2008. No amendments were filed in response to the final rejection mailed May 13, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per independent Claim 1 and dependent Claim 7 is an ultrasound system which acquires images of differently oriented image planes of a patient in rapid succession and a method of operating the ultrasound system of Claim 1, respectively. The invention is particularly useful for conducting a stress echo exam, in which images of different views of the heart are acquired when the patient is at rest and again when the heart is under stress, either by exercise or application of a pharmaceutical such as Dobutamine. Views of the heart which are typically acquired during a stress echo exam are the apical 4-chamber view, the apical 2-chamber view, the parasternal long axis view and the parasternal short axis view as listed in Tables 6-9 of one of the cited references, US Pat. 6,503,203 (Rafter et al.) The challenge of a stress echo exam occurs during the acquisition of the views during stress, when the desired views must all be acquired when the heart is beating very rapidly. The images must be quickly acquired before the heart rate declines from its peak stress heart rate. As stated in Rafter et

al. at col. 12, lines 3-7 and again at column 13, lines 45-48, these image views must be acquired within one minute or so. Prior to Rafter et al., acquisition of the image views required that the clinician move the ultrasound probe to aim at the desired image plane of the heart and adjust the ultrasound system image control settings to provide the necessary image quality (frame rate, depth, focus, etc.) for the new view. Rafter et al. improved on this by enabling the clinician to adjust the image control settings in advance and save them in a stress protocol. After the clinician acquired one view, the protocol would inform the clinician of the next view to acquire and would automatically invoke the saved image control settings for the next image, thus saving the time otherwise required to adjust the control settings. The clinician then only had to move the probe from one position on the body to the next to aim the probe at the next image plane of the protocol without the need to adjust the controls, which simplified the clinician's task and enabled more rapid view acquisition during stress. This operation of the Rafter et al. system is describe in the present application from page 5, line 10 through page 8, line 4. As stated in this passage, "In some ultrasound systems (*e.g.*, the Rafter et al. system) it is possible to save the image settings and the triggering interval sequence" and thus expedite the acquisition of the successively different views of the heart.

The present invention improves on the advances of Rafter et al. by employing a probe with a two dimensional (2D) array transducer {page 8, lines 8-10; Fig. 3, #500}. A 2D array can be programmed by its beamformer to steer its beams in any direction in three dimensions, enabling the acquisition of images in different orientations in the body in front of the probe without the need to move the probe on the body from a favorable acoustic window {page 10, lines 8-16; Fig. 3, #502, #116, #312}. A plane orientation control is coupled to the beamformer controller for adjustment of the orientations of a plurality of image planes relative to selected anatomy {page 11, lines 10-15; Fig. 3, #20}. The clinician manipulates this control to electronically steer the image planes through the desired planes of the heart, then saves the image plane orientations in a storage device {page 11, lines 18-21; Fig. 3, #22}. With the image plane orientations stored, the clinician begins the diagnostic exam. When the times come to acquire the necessary at-rest and stress images, the clinician actuates an acquisition control to initiate the acquisition of the sequence of image planes in the selected succession of different plane orientations {page 12, lines 14-19; Fig. 3, #20}. The preprogrammed sequence of images of different viewing perspectives with preset imaging settings and at the desired heart cycle intervals is then acquired automatically by the ultrasound system by use of the image

plane coordinate and timing parameters stored in the storage device {Fig. 3, #22} and accessed by the beamformer controller {Fig. 3, #312} {page 12, lines 19-25}. As stated on page 13, lines 2-6, the heart image acquisition process of the present invention can enable the stress echo exam to be completed in one-third of the time required by a conventional (*e.g.*, Rafter et al.) ultrasound system. Importantly, the need to manually reposition the probe for each new view of the heart has been eliminated.

Claim 7 describes the steps of aiming an image plane, reaiming the image plane with the plane orientation control from the same acoustic window, storing the plane orientation information, and initiating the sequence of image acquisition of the previously oriented image planes. These steps are presented in sequence in Fig. 4 at #104-#126 and described on page 10, line 34 through page 13, line 6 of the specification. Claim 15 is similar but with the additional requirements of introducing a contrast agent for the exam {page 12, lines 3-4}, and doing image acquisition in synchronism with a heart cycle waveform {page 12, lines 7-13}.

Mapping Claims 1 and 7 to the text and drawings of the application, it is seen that the claim elements are supported by the text and drawings as shown in brackets:

1. An ultrasonic diagnostic imaging system which acquires images of differently oriented image planes of a patient in rapid succession comprising:

a probe including a two dimensional array transducer {page 8, lines 8-10; Fig. 3, #500};

a beamformer, coupled to the array transducer, for scanning beams over a variety of different directions and inclinations with respect to the array transducer {page 10, lines 8-16; Fig. 3, #502, #116};

a beamformer controller programmable to scan beams over differently oriented image planes in a sequence of image planes until acquisition of the image planes has been completed {page 10, lines 8-16; Fig. 3, #312};

an image processor coupled to the beamformer{page 9, lines 7-13; Fig. 3, #318};

a display coupled to the image processor {page 9, line 33 through page 10, line 3; Fig. 3, #150};

a plane orientation control, coupled to the beamformer controller, for adjustment of the orientations of a plurality of image planes relative to selected anatomy {page 11, lines 10-15; Fig. 3, #20};

a storage device responsive to the plane orientation control and operative to store parameters of different image plane orientations selected by operation of the plane orientation control {page 11, lines 18-21; Fig. 3, #22}; and

an acquisition control, coupled to the beamformer and responsive to the stored parameters, for initiation in a diagnostic exam of the acquisition of a sequence of image planes in the selected succession of different orientations with respect to the selected anatomy {page 12, lines 14-19; Fig. 3, #20}.

7. A method for operating the ultrasonic diagnostic imaging system of Claim 1 to perform the acquisition of ultrasonic images of a plurality of differently oriented image planes in rapid succession comprising:

aiming a first image plane of a two dimensional array probe through an acoustic window of a body {page 10, line 30 to page 11, line 3; Fig. 4, #102, #104};

reaiming the image plane through the acoustic window by use of the plane orientation control to image a second image plane of a different orientation than the first image plane {page 11, lines 10-25; Fig. 4, #108-#114};

storing information defining the orientation of the second image plane in the storage device {page 11, lines 18-21 and lines 26-29; Fig. 4, #116}; and

initiating a sequence of image acquisition which acquires an image of the first image plane followed by an image of the second image plane by use of the stored information {page 12, lines 14-34; Fig. 4, #122-#126}.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-6 were correctly rejected under 35 U.S.C. §103(a) as unpatentable over US Pub. 2003/0195421 (Demers et al.) in view of US Pat. 6,503,203 (Rafter et al.); and

B. Whether Claims 7-20 were correctly rejected under 35 U.S.C. §103(a) as unpatentable over US Pub. 2003/0195421 (Demers et al.) in view of US Pat. 6,503,203 (Rafter et al.)

VII. ARGUMENT

A. Rejection of Claims 1-6 under 35 U.S.C. §103(a) as unpatentable over US Pub. 2003/0195421 (Demers et al.) in view of US Pat. 6,503,203 (Rafter et al.)

For the Board's information, the two cited references and the present application are all commonly assigned. The inventor in the present application is the first-named inventor of Rafter et al. The Demers et al. application was applied in the initial rejection as a §102 reference against Claims 1-9 and 14 and argued in the responsive amendment. Rafter et al. is newly applied in the final rejection.

While the final rejection only identifies Claims 1-9 and 14 as the finally rejected claims, it will be assumed in the argument below that the rejection was intended to be directed to all of Claims 1-20.

As recited above, Claim 1 describes an ultrasonic diagnostic imaging system which acquires images of differently oriented image planes of a patient in rapid succession comprising a probe including a two dimensional array transducer; a beamformer, coupled to the array transducer, for scanning beams over a variety of different directions and inclinations with respect to the array transducer; a beamformer controller programmable to scan beams over differently oriented image planes in a sequence of image planes until acquisition of the image planes has been completed; an image processor coupled to the beamformer; a display coupled to the image processor; a plane orientation control, coupled to the beamformer controller, for adjustment of the orientations of a plurality of image planes relative to selected anatomy; a storage device responsive to

the plane orientation control and operative to store parameters of different image plane orientations selected by operation of the plane orientation control; and an acquisition control, coupled to the beamformer and responsive to the stored parameters, for initiation in a diagnostic exam of the acquisition of a sequence of image planes in the selected succession of different orientations with respect to the selected anatomy. A clinician can, prior to an ultrasound exam, hold the probe against a favorable acoustic window of the body and steer a sequence of images to desired plane orientations with the plane orientation control. After the orientation of each image plane has been set, the plane orientations are stored in a storage device. When the diagnostic exam is underway and the clinician needs to acquire the pre-steered image planes, an acquisition control is actuated to initiate acquisition of a sequence of images in the pre-set plane orientations. Since the probe includes a 2D array, the images can be quickly and automatically electronically steered to their desired orientations and acquired in succession without moving the probe.

Demers et al. describe a predecessor to the present invention, which is a biplane ultrasound imaging system. In biplane imaging a 2D array probe alternately scans two differently oriented image planes and then displays the images of the two planes simultaneously side-by-side. In the biplane probe of Demers et al., the orientation of one of the biplane

images, the left image L in the illustrated example in Demers et al., is fixed in relation to the transducer array. The L image is always in a plane which is orthogonal to and extending from the center of the array. See Demers et al. at page 3, paragraph [0031]. This means that it is not possible to electronically steer the image plane of the L image; only the right image R can be changed in orientation. Thus it is not possible to adjust the orientations of a plurality of image planes as called for by Claim 1.

The biplane system of Demers et al. has no starting or stopping of its L and R image sequencing. Rather, it is continually scanning both image planes in alternating or interlaced succession. See page 3, paragraph [0029] of Demers et al. The alternate scanning continues even while the R image is being rotated or tilted; it never stops and cannot be triggered to start. Thus there is no acquisition control as called for by Claim 1. It is not possible to adjust the plane orientations and store the adjustments on a storage device to be used later as with the present invention. There is no acquisition control which can be actuated or triggered during a diagnostic exam to initiate acquisition of a sequence of images in the previously stored succession of different plane orientations.

The controlled initiation of the acquisition control in the present claimed invention means that acquisition can also be selectively triggered

by a physiological event such as a particular phase of the heart cycle using an ECG trigger signal. This is not possible in Demers et al., where acquisition is free-running and continuous. For all of these reasons it is respectfully submitted that Claim 1 and its dependent claims are patentable over Demers et al.

The Rafter et al. patent provides none of the deficiencies which are absent from Demers et al. except for ECG triggering. Rafter et al. are using a Sonos 5500 ultrasound system in their embodiments as referenced at column 6, lines 6-8, an ultrasound system which was made by the assignee of the present invention as successor to Agilent Technologies. The Sonos 5500 cannot use a 2D array transducer. All of the probes for this ultrasound system produce a single, fixed image plane which projects from the plane of the 1D array probes of that ultrasound system. This means that Rafter et al. lack the beamformer controller, the plane orientation control, a storage device of different image plane orientations, and an acquisition control as recited in Claim 1. Consistent with this are Tables 1-5 of Rafter et al., which list the parameters adjustable in a stress echo exam in Rafter et al. It can be seen that none of the parameters is or relates to a plane orientation parameter. That is because the plane orientation cannot be changed in a Rafter et al. probe. The single image plane always projects in a fixed position orthogonal to the center of the

face of the probe. When the clinician using the Rafter et al. system wants to acquire a differently oriented image plane, he or she must physically move the probe until the sole image plane intersects the desired plane of the heart. While Rafter et al. provide the advantage of storing and then replaying the imaging parameters of the state Tables, they still must physically move and re-aim the probe for each new view of the heart. After the clinician has acquired one image view, the clinician goes to the next step in a protocol, which tells the user the next view to be acquired. The clinician moves the probe to position the fixed image plane in line with the next required view of the heart and the system applies the imaging parameters for the new view. After the clinician has acquired the new view, the clinician goes to the next step in the protocol for the identification of the next view, and continues in the same manner. Thus, it is respectfully submitted that Rafter et al. is lacking even more of the elements of the present invention than are absent from Demers et al. For this reason it is respectfully submitted that the combination of Demers et al. and Rafter et al. cannot render Claims 1-6 unpatentable.

B. **Rejection of Claims 7-20 under 35 U.S.C. §103(a) as unpatentable over US Pub. 2003/0195421 (Demers et al.) in view of US Pat. 6,503,203 (Rafter et al.)**

Claim 7 describes a method for operating the ultrasonic diagnostic

imaging system of Claim 1 to perform the acquisition of ultrasonic images of a plurality of differently oriented image planes in rapid succession comprising aiming a first image plane of a two dimensional array probe through an acoustic window of a body; reaiming the image plane through the acoustic window by use of the plane orientation control to image a second image plane of a different orientation than the first image plane; storing information defining the orientation of the second image plane in the storage device; and initiating a sequence of image acquisition which acquires an image of the first image plane followed by an image of the second image plane by use of the stored information. Claim 7 depends from Claim 1 and is thus patentable over Demers et al. and Rafter et al. for the reasons stated above for Claim 1. In addition, Claim 7 recites the steps of an imaging procedure including aiming and reaiming the image plane through the same acoustic window of the body, storing the information defining the image plane orientation, and initiating a sequence of image acquisition which acquires the first image plane followed by the second image plane. In Demers et al. the biplane images are produced repeatedly and continuously. There is no ability to initiate a sequence of image acquisition because that function is not provided by Demers et al. This ability is absent from Rafter et al. also, which additionally does not use a 2D array probe, does not aim and reaim

the image plane from the same acoustic window, and has no ability to store image plane orientations because the probe in Rafter et al. only produces images with a single fixed image plane orientation, one extending orthogonal from the face of the probe. For these reasons it is respectfully submitted that Claim 7 and its dependent Claims 8-14 are patentable over the combination of Demers et al. and Rafter et al.

Claim 15 is similar to Claim 7 in that it depends from Claim 1 and is patentable for the same reasons as Claim 1. Claim 15 describes a method for operating the ultrasonic diagnostic imaging system of Claim 1 to acquire diagnostic ultrasound images of the heart comprising maintaining the two-dimensional array transducer in contact with an acoustic window of a body to image a first plane of the heart; imaging a second plane of the heart by selective change of the direction of beam scanning with the plane orientation control while maintaining the probe in contact with the acoustic window; storing information describing the orientations of the first and second planes in the storage device; introducing a contrast agent into the myocardium of the heart; acquiring a heart cycle waveform of the heart; and initiating acquisition of images of the first and second planes of the heart by use of the stored information and in synchronism with the heart cycle waveform. Like Claim 7, Claim 15 defines the steps of a diagnostic procedure including maintaining a 2D

array probe in contact with an acoustic window, imaging a first plane, imaging a second plane while maintaining the probe in contact with the same acoustic window, storing the orientations of the two planes, introducing a contrast agent, acquiring a heart waveform, and initiating acquisition of images by use of the stored orientation information and in synchronism with the heart waveform. The step of initiating is not possible in Demers et al. because the scanning of the biplanes is continuous and is not synchronized with a heart waveform. Rafter et al. also does not show or suggest the initiating step and further has no ability to image different planes from the same acoustic window or to store the orientation of the different planes because Rafter et al. can only scan one fixed plane in front of the probe. Features of dependent Claims 17 and 18 including skipping heart cycles before re-acquiring another set of images and acquiring images from different planes in successive heart cycles are also missing from Demers et al. and Rafter et al. For these reasons it is respectfully submitted that Claim 15 and its dependent Claims 16-20 are patentable over Demers et al. and Rafter et al.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-20 are patentable over Demers et al. and Rafter et al.

Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the July 24, 2008 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 1-20 are the claims involved in the appeal.

1. (rejected) An ultrasonic diagnostic imaging system which acquires images of differently oriented image planes of a patient in rapid succession comprising:

a probe including a two dimensional array transducer;

a beamformer, coupled to the array transducer, for scanning beams over a variety of different directions and inclinations with respect to the array transducer;

a beamformer controller programmable to scan beams over differently oriented image planes in a sequence of image planes until acquisition of the image planes has been completed;

an image processor coupled to the beamformer;

a display coupled to the image processor;

a plane orientation control, coupled to the beamformer controller, for adjustment of the orientations of a plurality of image planes relative to selected anatomy;

a storage device responsive to the plane orientation control and operative to store parameters of different image plane orientations selected by operation of the plane orientation control; and

an acquisition control, coupled to the beamformer and responsive to the stored parameters, for initiation in a diagnostic exam of the acquisition of a sequence of image planes in the selected succession of different orientations with respect to the selected anatomy.

2. (rejected) The ultrasonic diagnostic imaging system of Claim 1, further comprising a source of patient heart waveforms coupled to the beamformer controller.

3. (rejected) The ultrasonic diagnostic imaging system of Claim 1, wherein the image processor further comprises a contrast agent image processor.

4. (rejected) The ultrasonic diagnostic imaging system of Claim 1, wherein the plane orientation control further comprises a manually operated user control; and wherein the storage device further comprises:

a storage device for storing scanning parameters for a plurality of plane orientations selected by the user control.

5. (rejected) The ultrasonic diagnostic imaging system of Claim 4, further comprising a plurality of imaging parameters which may be adjusted by a user; and

wherein the storage device further comprises a storage device for storing adjusted imaging parameters.

6. (rejected) The ultrasonic diagnostic imaging system of Claim 5, wherein the beamformer controller is responsive to stored scanning parameters and imaging parameters upon activation of the acquisition control.

7. (rejected) A method for operating the ultrasonic diagnostic imaging system of Claim 1 to perform the acquisition of ultrasonic images of a plurality of differently oriented image planes in rapid succession comprising:

aiming a first image plane of a two dimensional array probe through an acoustic window of a body;

reaiming the image plane through the acoustic window by use of the plane orientation control to image a second image plane of a different orientation than the first image plane;

storing information defining the orientation of the second image plane in the storage device; and

initiating a sequence of image acquisition which acquires an image of the first image plane followed by an image of the second image plane by use of the stored information.

8. (rejected) The method of Claim 7, wherein reaiming further comprises reaiming the image plane through the same acoustic window as that of the first image plane.

9. (rejected) The method of Claim 8, further comprising storing information defining the orientation of the first image plane in the storage device,

wherein initiating further comprises using the stored information of the first image plane.

10. (previously rejected) The method of Claim 7, further comprising infusing the body with an ultrasonic contrast agent.

11. (previously rejected) The method of Claim 10, further comprising, following infusing, applying stress to the body and,

following applying, repeating the initiating step.

12. (previously rejected) The method of Claim 10, wherein the body comprises the heart and wherein the myocardium of the heart is infused with the contrast agent.

13. (previously rejected) The method of Claim 12, wherein, in the aiming and reaiming steps, the first image plane comprises one of an AP4, AP2, or AP3 view of the heart, and the second image plane comprises a different one of an AP4, AP2, or AP3 view of the heart.

14. (rejected) The method of Claim 7, further comprising adjusting an image parameter after at least one of the aiming and reaiming steps; and

storing the adjusted image parameter for each step,

wherein initiating further comprises using the stored adjusted image parameter during image acquisition.

15. (previously rejected) A method for operating the ultrasonic diagnostic imaging system of Claim 1 to acquire diagnostic ultrasound images of the heart comprising:

maintaining the two-dimensional array transducer in contact with an acoustic window of a body to image a first plane of the heart;

imaging a second plane of the heart by selective change of the

direction of beam scanning with the plane orientation control while maintaining the probe in contact with the acoustic window;

storing information describing the orientations of the first and second planes in the storage device;

introducing a contrast agent into the myocardium of the heart;

acquiring a heart cycle waveform of the heart; and

initiating acquisition of images of the first and second planes of the heart by use of the stored information and in synchronism with the heart cycle waveform.

16. (previously rejected) The method of Claim 15, wherein initiating acquisition further comprises acquiring images of the first and second planes during a single waveform.

17. (previously rejected) The method of Claim 16, wherein acquiring further comprises acquiring another set of images of the first and second planes a predetermined number of heart cycles following the first acquiring of images.

18. (previously rejected) The method of Claim 15, wherein initiating acquisition further comprises acquiring an image from a different plane in successive heart cycles.

19. (previously rejected) The method of Claim 15 further comprising:

following the first initiating acquisition of images of the first and second planes of the heart, increasing the heart rate; and

following increasing the heart rate, acquiring for a second time images of the first and second planes of the heart by use of the stored information and in synchronism with the heart cycle waveform.

20. (previously rejected) The method of Claim 16, wherein acquiring images of the first and second planes of the heart further comprises acquiring less than all of the scanlines of the first and second planes alternately until complete images of the first and second planes have been acquired.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS

None. There are no related proceedings.